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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,395	06/23/2003	Charles L. Guy	UF-326XC1	1698

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EXAMINER	
KUMAR, VINOD	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 03/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/602,395	GUY ET AL.	
	Examiner	Art Unit	
	Vinod Kumar	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-39* is/are pending in the application.

4a) Of the above claim(s) *40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 June 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *November 17, 2003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 1-39, and enzyme species β-amylase in the paper filed December 9, 2005 is acknowledged.

The subject matter of species restricted in the Office Action mailed on November 3, 2005 has been found to be over-lapping and searching all the species listed in claims 5 and 24 together should not result in undue search burden for the Examiner. Thus, the restriction requirement for election of species is withdrawn. Accordingly the claims 1-39, along with all of species listed in claims 5 and 24 are being examined in the instant Office action. The election of species requirement has been WITHDRAWN. Claim 40 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. This restriction is made FINAL.

Information Disclosure Statement

2. An initialed and dated copy of Applicant's IDS form 1449 filed November 17, 2003 is attached to the instant Office action.

The listing of references in the specification (pages 29-34) is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 20-30 and 33-39 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 20 reads on a plant, plant tissue, or plant cell can be bred, which are found in nature and thus, are unpatentable to Applicant. The plant, plant tissue, or plant, as claimed in claim 20, have the same characteristics as those found naturally occurring plant, plant tissue, or plant cell thereof and therefore does not constitute patentable subject matter. See *American Wood v. Fiber Disintegrating Co.*, 90 U.S. 566 (1974), *American Fruit Growers v. Brodgex Co.*, 283 U.S. 2 (1931), *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 33 U.S. 127 (1948), *Diamond v. Chakrabarty*, 206 USPQ 193 (1980).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite, because the last step of the method is consistent with the preamble. Line 1 says the method is for increasing resistance of a plant to an environmental stress. But the last step only results in introduction of a polypeptide into the plant.

Claims 6 and 25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation for "reduced inhibition by maltose", as the recitation is unclear. The metes and bounds of the claims are not clear.

Claims 7 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation "thermostable". It is unclear what temperature are to be used to determine if the enzyme is thermostable. The metes and bounds of the claim are unclear.

Claims 14 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation "promoter drives increased expression". It is unclear what is the difference between driving expression and driving increased expression?

Claims 19 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation "relative to a plant when said polynucleotide has not been introduced". It is unclear whether the plant of the recitation is same variety as that claimed or can it be any plant. It is suggested to insert --of the same variety,-- after "plant" and before "wherein".

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the recitation "bred", which is confusing, as it is unclear how a plant tissue or plant cell is bred. It is also clear from said recitation what is intended.

Appropriate corrections or clarifications are required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-39, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a stress resistant transgenic plant or a method for producing said transgenic plant comprising expression of a polynucleotide encoding α- or β-amylase that catalyzes the production of maltose, does not provide enablement for a transgenic plant or a method of producing said plant with increased resistance to stress comprising expression of a polynucleotide encoding enzymatically active fragments of α-amylase or β-amylase, or other enzymes that catalyze the production of maltose or maltose alcohol. The claims contain subject matter which was not described in the specification in such a way as to enable any person skilled in the art to which it pertains, with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are broadly drawn to a transgenic plant or a method of producing said transgenic plant with increased tolerance to an environmental stress comprising introducing a polynucleotide encoding a polypeptide that produces or catalyzes the production of maltose or maltose alcohol, or wherein said polypeptide is α-amylase, β-amylase, starch phosphorylase, starch debranching enzyme or an enzymatically active fragment thereof, or wherein β-amylase enzyme exhibits reduced inhibition by maltose, or wherein β-amylase enzyme is thermostable.

The specification teaches that heat and cold shock elicits β-amylase gene induction, and β-amylase expression is correlated with maltose accumulation (Examples 1 and 2, pages 23-25). Furthermore specification teaches maltose has compatible solute properties and can function as chloroplast stromal compatible solute *in vitro.* (Examples 3-4, pages 26-27).

Claims 1and 20 encompass a method of producing a stress resistant transgenic plant comprising a nucleic acid sequence that encode for any polypeptide that catalyze the synthesis of maltose or maltose alcohol or a plant, tissue, or cell transformed with or bred to contain said nucleic acid sequence. The specification does provide guidance in using a nucleic acid sequence encoding for β-amylase in a method of producing transgenic plant with increased stress resistance. It is also well established in the art that α- and β-amylase genes are up-regulated in response to stress. See Rizhsky et al. (Plant Physiol., 134:1683-1696, 2004). However, neither the prior art nor the specification teaches that maltose or maltose alcohol producing enzymes other than α- and β-amylases respond to stress. It is highly unpredictable whether starch degrading enzymes may participate in catalyzing the production of maltose when overexpressed in a transgenic plant to produce a stress resistance phenotype, given the prior art and the specification do not teach structure and function stability of such enzymes under stress conditions. Thus, it is highly unpredictable that a nucleic acid encoding for a polypeptide other than α- and β-amylases can be used in a method to produce stress tolerant plants when expressed in a transgenic plant. Undue experimentation by a skilled artisan is required to determine how such nucleic acids that do not encode for α- or β-amylase can be used in a method to produce a transgenic plant with stress resistant phenotype.

The method of claim 5 and the plant of claim 24 encompass a polynucleotide coding for any enzymatically active fragment of α-amylase, β-amylase, starch phosphorylase, or starch debranching enzyme (DBE). The specification provides no guidance on how such truncated version(s) of said polypeptides can be produced that

retain functional activity, and which can be used in a method of producing a transgenic plant with increased stress resistance phenotype.

Guo et al. (PNAS, 101: 9205-9210, 2004) teach that there is a probability factor of 34% that a random amino acid replacement in a given protein will lead to its functional inactivation. In the instant case, such a probability factor will be much higher as truncated version(s) of above described fragments would encompass more than single amino acid changes of the encoded polypeptide for said maltose or maltose alcohol producing enzymes.

Thus, it is highly unpredictable to make fragment(s) of any maltose producing enzyme included that are listed in claims 5 and 24 that retain functional activity. In the absence of further guidance, undue experimentation is required by one skilled in the art to determine how such fragment(s) can be designed so that they retain stable structure function stability when overexpressed in a transgenic plant, and are able to catalyze the production of maltose to produce a stress resistant phenotype in the transgenic plant.

Claims 6 and 25 encompass a method that requires a polynucleotide encoding an altered polypeptide exhibiting β-amylase activity with reduced inhibition by maltose. The specification provides no guidance how an amino acid sequence encoding for wild type β-amylase could be altered so that the modified polypeptide retains structure and function stability and exhibits reduced inhibition by maltose when overexpressed in a transgenic plant to produce stress resistant phenotype.

Claims 7 and 26 encompass an altered polypeptide of β-amylase with thermostable property. The specification provides no guidance how an amino acid sequence for wild type β-amylase could be altered so that the modified polypeptide

retains structure and function stability and exhibits thermostable property when overexpressed in a transgenic plant to produce stress resistant phenotype.

Thus it is highly unpredictable what changes are necessary to produce a polynucleotide sequence that codes for an altered amino acid sequence of β-amylase, exhibiting reduced inhibition to maltose or thermostable property without affecting β-amylase activity. Undue experimentation is required by one skilled in the art to determine which part(s) of the β-amylase polypeptide can be altered without affecting structure functional stability of the modified protein when overexpressed in a transgenic plant to produce a stress resistant phenotype.

Neither the state of art nor the specification provides guidance as to how such an altered β-amylases can be made, other than random trial and error. The specification does not provide any guidance on what amino acid changes need to be made to produce an β-amylase that has reduced inhibition by maltose, or is thermostable. inoperable embodiments can be readily eliminated other than random trial and error. See Genentech, Inc. v. Novo Nordisk, A/S, USPQ2d 1001, 1005 (Fed. Cir. 1997), which teaches that "the specification, not the knowledge of one skilled in the art" must supply the enabling aspects of the invention.

Given the breadth of the claims, unpredictability of the art and lack of guidance of the specification, as discussed above, undue experimentation would be required by one skilled in the art to make and use of claimed invention.

6. Claims 1-39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are broadly drawn to a transgenic plant or a method of producing said transgenic plant with increased tolerance to an environmental stress comprising introducing a polynucleotide encoding a polypeptide that produces or catalyzes the production of maltose or maltose alcohol, or wherein said polypeptide is α-amylase, β-amylase, starch phosphorylase, starch debranching enzyme or an enzymatically active fragment thereof, or wherein β-amylase enzyme exhibits reduced inhibition by maltose, or wherein β-amylase enzyme is thermostable.

The specification teaches that heat and cold shock elicits β-amylase gene induction, and β-amylase expression is correlated with maltose accumulation (Examples 1 and 2 , pages 23-25). Furthermore specification teaches maltose has compatible solute properties and can function as chloroplast stromal compatible solute *in vitro.* (Examples 3-4, pages 26-27).

Claims 1 and 20 encompass a method of producing a stress resistant transgenic plant comprising any nucleic acid sequence that encodes for any polypeptide that catalyze the synthesis of maltose or maltose alcohol or a plant, tissue, or cell transformed with said nucleic acid exhibiting a stress resistant phenotype. The method of claim 5 and the plant of claim 24 encompass a polynucleotide coding for any enzymatically active fragment of α-amylase, β-amylase, starch phosphorylase, or starch debranching enzyme (DBE). Prior art and specification does describe that a nucleic acid encoding α- or β-amylase can be correlated with the function of conferring increased stress response, when expressed in a transgenic plant. However, the specification fails to disclose and correlate the structures of polynucleotides encoding

for polypeptides other than α or β-amylase to a function of producing stress resistant phenotype when overexpressed in a transgenic plant. Likewise the specification fails to disclose structures that are not 100% identical to unaltered α-amylase, β-amylase, starch phosphorylase, starch debranching enzyme (DBE) polypeptides, but which retain their enzymatic activity. Applicants have not correlated the structures of the species of the broadly claimed genus to a common function of producing, catalyzing the synthesis of, or resulting in the production of maltose or maltose alcohol, and conferring increased resistance to any and all environmental stresses to a transgenic plant. The specification does not indicate that Applicants had reduced all the embodiments of claimed invention to practice. Accordingly, there is lack of adequate description to inform a skilled artisan that applicant was in possession of the claimed invention at the time of filing. See Written Description guidelines published in Federal Register/Vol.66, No. 4/Friday, January 5, 2001/Notices; p. 1099-1111.

Given the claim breadth and lack of guidance as discussed above, the specification does not provide written description of the genus broadly claimed. Accordingly, one skilled in the art would not have recognized Applicants to have been in possession of the claimed invention at the time of filing.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. The claims 1, 5, 9, 10, 14-20, 24, 28-29 and 33-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Gausing et al. (United States Patent No. 5,498,832, Issued March 12, 1996), and evidenced by Rizhsky et al. (Plant Physiology, 134:1683-1696, 2004)

Claims are broadly drawn to a transgenic plant with increased resistance to an environmental stress condition and a method of producing said transgenic plant comprising introducing a polynucleotide encoding a polypeptide that catalyzes or results in the production of maltose, or wherein said polynucleotide comprises a promoter operably linked to said coding region of said polynucleotide, or wherein said promoter drives increased expression of said coding region of said polynucleotide, or wherein said promoter is inducible or wherein said plant is monocot or dicot.

Gausing et al. teach a transgenic plant and a method of producing said transgenic plant comprising introducing a polynucleotide encoding for alpha-amylase, operably linked to a promoter that drives the increased expression of alpha-amylase coding region, wherein the transformed plant could be potato (dicot) or rice (monocot), or wherein promoter is inducible. See claims 20-31; Figures 1-4; column 18, lines 3-10; column 22, lines 34-67; column 23; column 24, lines 1-13. The property of producing maltose by the enzymatic action of an amylase is inherent to the polypeptide taught by reference. Although Gausing et al. do not teach a stress resistant transgenic plant, such modification would be inherent to the method of producing a transgenic plant overexpressing a polypeptide that catalyzes the synthesis of maltose, a compatible solute involved in stress response as evidenced by Rizhsky et al. who teach that a plant exhibits increased alpha and beta amylase expression activities accompanied with increased accumulation of maltose during a response to environmental stresses (see

Abstract and Tables I and II, in particular see page 1687, Gene No. At3g23920; page 1688, Gene No. At4g25000; page 1692.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The Claims 1-5, 7-11, 14-21, 23-30, 33-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gausing et al. (United States Patent No. 5,498,832, Issued March 12, 1996), in view of Seki et al. (The Plant Cell, 13: 61-72, 2001).

Claims are broadly drawn to a transgenic plant with increased resistance to an environmental stress condition and a method of producing said transgenic plant comprising introducing a polynucleotide encoding a polypeptide that catalyzes or results in the production of maltose, or wherein said polynucleotide comprises a promoter operably linked to said coding region of said polynucleotide, or wherein said promoter drives increased expression of said coding region of said polynucleotide, or wherein said plant is monocot or dicot, or wherein polypeptide encoded by said polynucleotide comprises an amino acid sequence that targets said polypeptide to chloroplast, or wherein said polypeptide is a β-amylase, or wherein said environmental stress is heat or cold stress.

Gausing et al. teach a transgenic plant and a method of producing said transgenic plant comprising introducing a polynucleotide encoding for alpha-amylase, operably linked to a promoter that drives the increased expression of alpha-amylase

coding region, wherein the transformed plant could be potato (dicot) or rice (monocot), or wherein promoter is inducible. See claims 20-31; Figures 1-4; column 18, lines 3-10; column 22, lines 34-67; column 23; column 24, lines 1-13.

Gausing et al. do not teach chloroplast targeted β-amylase.

Seki et al. teach increased expression of β-amylase gene encoding a polypeptide comprising an amino acid sequence that targets said polypeptide for chloroplast localization wherein overexpression of said polypeptide is in response to cold stress to the plant. See Page 63, column 2 and 2nd paragraph. Also see gene FL5-90, GenBank Accession No. AB050575 in Table 2 on Page 66.

Given that Gausing et al. teach a method of producing a transgenic plant expressing an enzyme α-amylase that degrades starch into maltose and Seki et al. teach that starch degrading enzyme like chloroplast targeted β-amylase levels are up regulated in response to environmental stress, it would have been prima facie obvious to one skilled in the art at the time the invention was made to add a cold or thermal step to the method of producing a transgenic plant comprising expressing a maltose producing enzyme α-amylase as taught by Gausing et al., given the goal of increasing the tolerance of a plant to environmental stress involving modifying the levels of polypeptides involved in production of maltose in a cell. Accordingly, one skilled in the art would have been motivated to generate the claimed invention with a reasonable expectation of success.

It would have been prima facie obvious to one skilled in the art at the time the invention was made to use a polynucleotide encoding an amylase polypeptide comprising an amino acid sequence that targets said polypeptide to chloroplast, in a method to express said amylase under inducible promoter in a transgenic plant as

taught by Gausing et al. One of the ordinary skill in the art would have been motivated to use the polynucleotide encoding a polypeptide comprising an amino acid sequence for chloroplast targeted β-amylase as taught by Seki et al., given the starch, a substrate for amylase is predominately stored in chloroplast that can be readily hydrolyzed by said β-amylase to release enough maltose to provide resistance against environmental stress.

Thus, the claimed invention would have been prima facie obvious as a whole to one of ordinary skill in the art at the time the invention was made.

9. The Claims 1-5, 8-24 and 28-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gausing et al. (United States Patent No. 5,498,832, Issued March 12, 1996) in view of Seki et al. (The Plant Cell, 13: 61-72, 2001) and Grover et al. (Current Science, 80:206-216, January 2001).

Teachings of Gausing et al. are discussed supra.

Teachings of Seki et al. are discussed supra.

Gausing et al. and Seki et al. do not teach use of stress responsive promoters.

Grover et al. teach that using stress inducible promoter can results in minimal negative effects on the growth of a transgenic plant overexpressing a stress tolerant gene, while providing greater tolerance to stress compared to a constitutive promoter. See Page 210 and Table 2.

Given that Gausing et al. teach a method of producing a transgenic plant expressing an enzyme that degrades starch into maltose and Seki et al. teach that starch degrading enzyme like chloroplast targeted β-amylase levels are up regulated in response to environmental stress, it would have been prima facie obvious to one skilled in the art at the time the invention was made to modify the method of Gausing et al. in

expressing a polypeptide that degrades starch to release maltose using the stress responsive promoters like Cor78 or hsp17.6. The motivation to so comes from Gover et al. who teach the usefulness of expressing stress responsive genes under stress inducible promoter like cor78 or hsp 17.6 to produce a stress resistant transgenic plant with normal growth characteristics.

Thus, the claimed invention as a whole was prima facie obvious over the combined teachings of the prior art.

Conclusions

10. No claims are allowed. Claims 1-39 are not free from prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vinod Kumar whose telephone number is (571) 272-4445. The examiner can normally be reached on 8.30 a.m. to 5.00 pm.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ASHWIN D. MEHTA, PH.D.
PRIMARY EXAMINER